

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Atty. Docket No.:

001107.00363

Elizabeth Jaffee et al.

Serial No.:

10/618,088

Group Art Unit:

TBD

Filed:

July 14, 2003

Examiner:

TBD

For:

Mesothelin Vaccines and Model Systems

<u>INFORMATION DISCLOSURE STATEMENT</u>

Commissioner for Patents P.O. Box 1450 Alexandria, VA. 22313

Dear Sir:

Submitted herewith are eight (8) sheets of Form PTO-1449. A copy of each of the references listed therein is enclosed. It is respectfully requested that the Examiner make his/her consideration of each of these documents formally of record.

Since this Information Disclosure Statement is being filed before issuance of a first Office Action on the merits under 37 C.F.R. 1.97(b), it is submitted that no fee or certification is required. However, if a fee is required, please charge our deposit account no. 19-0733.

By:

Respectfully submitted,

BANNER & WITCOFF, LTD

Dated: September 11, 2003

Sarah A. Kagan

Registration No. 32,141

Banner & Witcoff, Ltd. Customer No. 22907

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number 10/618,088

Filing Date July 14, 2003

First Named Inventor Elizabeth Jaffee

Group Art Unit TBD

Examiner Name TBD

Attorney Docket Number 001107.00363

(use as many sheets as necessary)
Sheet 1 of 8

Examiner	Cite No.1		Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevar
Initials *			MM-DD-YYYY	Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5,723,318	03/03/1998	Yamaguchi et al.	
		5,763,183	06/09/1998	Pesonen et al.	
		5,795,872	08/18/1998	Ricigliano et al.	
		5,830,463	11/03/1998	Duke et al.	
·		5,951,976	09/14/1999	Segal	
		5,981,259	11/09/1999	Franzusoff	
		6,083,502	07/04/2000	Pastan et al.	
		6,153,430	11/28/2000	Pastan et al.	
		6,171,777	01/09/2001	Cook et al.	
		6,224,868	05/01/2001	Wong et al.	
		6,270,795	08/07/2001	Jones et al.	
		6,358,933	03/19/2002	Aguilar Rubido et al.	
		6,384,018	05/07/2002	Content et al.	
		6,448,086	09/10/2002	Khosravi et al.	
		6,472,375	10/29/2002	Hoon et al.	
		6,475,995	11/05/2002	Roy et al.	
		6,488,926	12/03/2002	Khan et al.	.,
		6,495,143	12/17/2002	Lee et al.	
		6,500,432	12/31/2002	Dalemans et al.	
		20020034753	03/21/2002	Yang et al.	
		20020051990	05/02/2002	Ople et al.	

	FOREIGN PATENT DOCUMENTS					
Examiner Initials*	0.1	Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines,	
	Cite No. ¹	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵
		WO 97/25068	07/17/1997			
		WO 99/28471	06/10/1999			
		WO 00/50900	08/31/2000			
		WO 00/73346	12/07/2000			

Examiner Signature	Date Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Applicant's unique citation designation number (optional) . ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.
³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

2

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of 8

Complete if Known **Application Number** 10/618,088 Filing Date July 14, 2003 First Named Inventor Elizabeth Jaffee **Group Art Unit TBD Examiner Name TBD Attorney Docket Number** 001107.00363

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	,
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		ANGELAKOPOULOS et al., "Safety and Shedding of an Attenuated Strain of Listeria monocytogenes with a Deletion of actA/plcB in Adult Volunteers: a Dose Escalation Study of Oral Inoculation", Infection and Immunity, July 2002, pp. 3592-3601, Vol. 70, No. 7.	
		ARGANI et al., "Mesothelin Is Overexpressed in the Vast Majority of Ductal Adenocarcinomas of the Pancreas: Identification of a New Pancreatic Cancer Marker by Serial Analysis of Gene Expression (SAGE)*, Clinical Cancer Research, December 2001, pp. 3862-3868, Vol. 7.	
	~	ARRINGTON et al., "Plasmid Vectors Encoding Cholera Toxin or the Heat-Labile Enterotoxin from Escherichia coli Are Strong Adjuvants fro DNA Vaccines", Journal of Virology, May 2002, pp. 4536-4546, Vol. 76, No. 9.	
		BALTZ, "Vaccines in the treatment of cancer", Am J Health-Syst Pharm, Nov 15 1995, pp. 2574-2585, Vol. 52.	
		BERA et al., "Mesothelin Is Not Required for Normal Mouse Development or Reproduction", <i>Molecular and Cellular Biology</i> , April 2000, pp. 2902-2906, Vol. 20, No. 8.	
		CHANG et al., "Flavivirus DNA Vaccines Current Status and Potential", Ann New York Acad Sci., Dec 2001, pp. 272-85, Vol 951.	
		CHOWDHURY et al., "Analysis of cloned Fvs from a phage display library indicates that DNA immunization can mimic antibody response generated by cell immunizations", JIM, 1999, pp. 83-91, Vol. 231.	
		CHOWDHURY et al., "Generation of high titer antisera in rabbits by DNA immunization", <i>JIM</i> , 2001, pp. 147-154, Vol. 249.	
		CHOWDHURY et al., "Isolation of a high-affinity stable single-chain Fv specific for mesothelin from DNA-immunized mice by phage display and construction of a recombinant immunotoxin with anti-tumor activity", <i>Proc. Natl. Acad. Sci. USA</i> , January 1998, pp. 669-674, Vol. 95.	
		COHEN et al., "Modulating the immune response to genetic immunization", "The FASEB Journal, December 1998, pp. 1611-1626, Vol. 12.	
		DARJI et al., "Oral Somatic Transgene Vaccination Using Attenuated S. typhimurium, Cell, Dec 12 1997, pp. 765-775, Vol. 91.	
		DARJI et al., "Oral delivery of DNA vaccines using attenuated Salmonella typhimurium as carrier", FEMS Immunology and Medical Microbiology, 2000, pp. 341-349, Vol. 27.	
		GLOMSKI et al., "The Listeria monocytogenes hemolysin has an acidic pH optimum to compartmentalize activity and prevent damage to infected host cells", The Journal of Cell Biology, Mar 18 2002, pp. 1029-1038, Vol. 156, No. 6.	
		GUNN et al., "Two Listeria monocytogenes Vaccine Vectors That Express Different Molecular Forms of Human Papilloma Virus-16 (HPV-16) E7 Induce Qualitatively Different T Cell Immunity That Correlates with Their Ability to Induce Regression of Established Tumors Immortalized by HPV-16", The Journal of Immunology, 2001, pp. 6471-6479, Vol. 167	

Examiner	Date	
Signature	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Sheet

PTO/SB/08B(10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Substitute for form 1449A/PTO

	Complete if Known	
Application Number	10/618,088	
Filing Date	July 14, 2003	
First Named Inventor	Elizabeth Jaffee	
Group Art Unit	TBD	
Examiner Name	TBD	
Attorney Docket Number	001107.00363	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		HELLSTRÖM et al., "Tumor Immunology: An Overview", Ann. New York Acad. Sci., 1993, pp. 24-33, Vol. 690.	
		LAUER et al., "Construction, Characterization, and Use of Two Listeria monocytogenes Site-Specific Phage Integration Vectors", Journal of Bacteriology, Aug 2002, pp. 4177-4186, Vol. 184, No. 15.	
		LIAU et al., "Tumor Immunity within the Central Nervous System Stimulated by Recombinant Listeria monocytogenes Vaccination", Cancer Research, Apr 15 2002, pp. 2287-2293, Vol. 62.	
		MAKITALO et al., "ELISpot and ELISA analysis of spontaneous, mitogen-induced and antigen-specific cytokine production in cynomolgus and rhesus macaques", <i>JIM</i> , 2002, pp. 85-97, Vol. 270.	
		MEDINA et al., "Use of live bacterial vaccine vectors for antigen delivery: potential and limitations", Vaccine, 2001, pp. 1573-1580, Vol. 19.	
		PAN et al., "Regressin of Established B16F10 Melanoma with a Recombinant Listeria monocytogenes Vaccine", Cancer Research, Oct 15 1999, pp. 5264-5269, Vol. 59	
		POLAND et al., "Science, medicine, and the future New vaccine development", <i>BMJ</i> , June 2002, pp. 1315-1319, Vol. 324.	
		PORTNOY et al., "The cell biology of <i>Listeria monocytogenes</i> infection: the intersection of bacterial pathogenesis and cell-mediated immunity", <i>JCB</i> , Aug 5 2002, pp. 409-414, Vol. 158, No. 3	
		RUBIO-GODOY et al., "Discrepancy between ELISPOT IFN-y secretion and binding of A2/peptide multimers to TCR reveals interclonal dissociation of CTL effector function from TCR-peptide/MHC complexes half-life", <i>Proc. Natl. Acad. Sci. USA</i> , Aug 28 2001, pp. 10302-10307, Vol. 98, No. 18.	
		RYU et al., "Relationships and Differentially Expressed Genes among Pancreatic Cancers Examined by Large-scale Serial Analysis of Gene Expression", Cancer Research, Feb 1 2002, pp. 819-826, Vol. 62.	
		SCHOLLER et al., "Soluble member(s) of the mesothelin/megakaryocyte potentiating factor family are detectable in sera from patients with ovarian carcinoma", <i>Proc. Natl. Acad. Sci. USA</i> , September 1999, pp. 11531-11536, Vol. 96.	

Examiner Signature	Date Consider	red

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet of

	Complete if Known	
Application Number	10/618,088	
Filing Date	July 14, 2003	
First Named Inventor	Elizabeth Jaffee	
Group Art Unit	TBD	
Examiner Name	TBD	
Attorney Docket Number	001107.00363	

	7	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		SHEN et al., "Compartmentalization of Bacterial Antigens: Differential Effects on Priming of CD8 T Cells and Protective Immunity", Cell, Feb 20 1998, pp. 535-545, Vol. 92.	
		SHEN et al., "Recombinant <i>Listeria monocytogenes</i> as a live vaccine vehicle for the induction of protective antiviral cell-mediated immunity", <i>Proc. Natl. Acad. Sci. USA</i> , April 1995, pp. 3987-3991, Vol. 92.	
		STUBBS et al., "Whole recombinant yeast vaccine activates dendritic cells and elicits protective cell-mediated immunity", Nature Medicine, May 2001, pp. 625-629, Vol. 7, No. 5.	
		VECINO et al., "Mucosal DNA vaccination with highly attenuated Shigella is superior to attenuated Salmonella and comparable to intramuscular DNA vaccination for T cells against HIV", Immunology Letters, 2002, pp. 197-204, Vol. 82.	
		WARD et al., "Immunotherapeutic potential of whole tumour cells", Cancer Immunology, 2002.	
		WEISS et al., "Transfer of eukaryotic expression plasmids to mammalian host cells by bacterial carriers", Current Opinion in Biotechnology, 2001, pp. 467-472, Vol. 12.	
		ARRINGTON et al., "Plasmid vectors encoding cholera toxin or the heat-labile enterotoxin from Escherichia coli are strong adjuvants for DNA vaccines", <i>J Virol</i> 2002 May; 76(9):4536-46 (Abstract only)	
		ARVILOMMI H., "ELISPOT for detecting antibody-secreting cells in response to infections and vaccination", APMIS 1996 Jun; 104(6):401-10 (Abstract only)	
		AZEVEDO et al., "Main features of DNA-based immunization vectors", <i>Braz J Med Biol Res</i> 1999 Feb; 32(2):147-53 (Abstract only)	
		BERA TK et al., "Mesothelin is not required for normal mouse development or reproduction", <i>Mol Cell Biol</i> 2000 Apr; 20(8):2902-6 (Abstract only)	
		BRAMSON et al., "The efficacy of genetic vaccination is dependent upon the nature of the vector system and antigen", Expert Opin Biol Ther 2002 Jan;2(1):75-85 (Abstract only)	

Examiner	Date	
Signature		
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B(10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known Application Number 10/618,088 INFORMATION DISCLOSURE Filing Date July 14, 2003 STATEMENT BY APPLICANT First Named Inventor Elizabeth Jaffee **Group Art Unit TBD** (use as many sheets as necessary) **Examiner Name** TBD Sheet 5 Attorney Docket Number 001107.00363 of 8

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *			Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		CHANG GJ et al., *Flavivirus DNA vaccines: current status and potential*, Ann N Y Acad Sci 2001 Dec;951:272-85 (Abstract only)		
		COHEN et al., "Modulating the immune response to genetic immunization", FASEB J 1998 Dec;12(15):1611-26 (Abstract only)		
		COHEN EP, "DNA-based vaccines for the treatment of cancer – an experimental model", <i>Trends Mol Med</i> 2001 Apr;7(4):175-9 (Abstract only)		
		EDGEWORTH et al., "Vaccine development against HIV-1: current perspectives and future directions", Immunol Res 2002;25(1):53-74 (Abstract only)		
		FELTQUATE DM, "DNA vaccines: vector design, delivery, and antigen presentation", <i>J Cell Biochem Suppl</i> 1998;30-31:304-11 (Abstract only)		
		HASSAN et al., "Antitumor Activity of SS(dsFv)PE38 and SS1(dsFv)PE38, Recombinant Antimesothelin Immunotoxins against Human Gynecologic Cancers Grown in Organotypic Culture in Vitro", Clin Cancer Res 2002 Nov;8(11):3520-3526 (Abstract only)		
		HASSAN et al., "Anti-tumor activity of K1-LysPE38QQR, an immunotoxin targeting mesothelin, a cell-surface antigen overexpressed in ovarian cancer and malignant mesothelioma", <i>J Immunother</i> 200 Jul-Aug;23(4):473-9 (Abstract only)		
		HAUPT et al., "The potential of DNA vaccination against tumor-associated antigens for antitumor therapy", Exp Biol Med (Maywood) 2002 Apr;227(4):227-37 (Abstract only)		
		HAVRANEK et al., "Advances in prostate cancer Immunotherapy", Surg Oncol 2002 Jun;11(1-2):35-45 (Abstract only)		
		HELLSTROM I., "Nucleic Acid Vaccines for Chemoprevention of Ovarian Cancer", Grant No. 5P50CA083636-040002 (Abstract only)		
		HELLSTROM I., "Mesothelin Antigens for Diagnosis/Therapy of Ovarian Cancer", Grant No. 5R01CA085780-03 (Abstract only)		

Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DÓ NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 6 of

Complete if Known		
Application Number	10/618,088	
Filing Date	July 14, 2003	
First Named Inventor	Elizabeth Jaffee	
Group Art Unit	TBD	
Examiner Name	TBD	
Attorney Docket Number	001107.00363	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		HIPPO et al., "Differential gene expression profiles of scirrhous gastric cancer cells with high metastatic potential to peritoneum or lymph nodes", Cancer Res 2001 Feb 1;61(3):889-95 (Abstract only)	
		HOUGH et al., "Large-scale serial analysis of gene expression reveals genes differentially expressed in ovarian cancer", Cancer Res 2000 Nov 15;60(22):6281-7 (Abstract only)	
		KAUFMAN et al., "Immunotherapy for pancreatic cancer: current concepts", Hematol Oncol Clin North Am 2002 Feb;16(1):159-97, viii (Abstract only)	
		LUNDSTROM K., "Alphavirus vectors for gene therapy applications" Curr Gene Ther 2001 May;1(1):19-29 (Abstract only)	
		MAKITALO et al., "ELISpot and ELISA analysis of spontaneous, mitogen-induced and antigen-specific cytokine production in cynomolgus and rhesus macaques", <i>J Immunol Methods</i> 2002 Dec1;270(1):85-97 (Abstract only)	
		MASHISHI et al., "The ELISPOT assay: an easily transferable method for measuring cellular responses and identifying T cell epitopes", Clin Chem Lab Med 2002 Sep;40(9):903-10 (Abstract only)	
		MITCHELL MS., "Cancer vaccines, a critical review – Part I", Curr Opin Investig Drugs 2002 Jan;3(1):140-9 (Abstract only)	
		MONATH TP., "Japanese encephalitis vaccines: current vaccines and future prospects", Curr Top Microbiol Immunol 2002;267:105-38 (Abstract only)	
		MONZAVI-KARBASSI et al., "Current concepts in cancer vaccine strategies", <i>Biotechniques</i> 2001 Jan;30(1):170-2, 174, 176 (Abstract only)	
		MORROW et al., "Recombinant viruses as vectors for mucosal immunity", Curr Top Microbiol Immunol 1999;236:255-73 (Abstract only)	
		POLAND et al., "New vaccine development", BMJ 2002 Jun 1;324(7349):1315-9 (Abstract only)	

Examiner	Date
10:	Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Complete if Known

TRAD MARTIN Destitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

SEP 1 1 2003

Application Number

(use as many sheets as necessary) 7 Sheet

Filing Date	July 14, 2003	
First Named Inventor	Elizabeth Jaffee	
Group Art Unit	TBD	
Examiner Name	TBD	
Attorney Docket Number	001107.00363	_

10/618,088

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		POLO et al., "Alphavirus DNA and particle replicons for vaccines and gene therapy", Dev Biol (Basel) 2000;104:181-5 (Abstract only)	
		PRAZERES et al., "Purification of plasmids for gene therapy and DNA vaccination", <i>Biotechnol Annu Rev</i> 2001;7:1-30 (Abstract Only)	
		LINDSLEY et al., "Immunoprophylaxis of hepatitis C virus infection", Clin Liver Dis 2001 Nov;5(4):1091-103 (Abstract Only)	
		RAMSAY et al., "Genetic vaccination strategies for enhanced cellular, humoral and mucosal immunity", <i>Immunol Rev</i> 1999 Oct;171:27-44 (Abstract Only)	
		REIMANN et al., "DNA vaccines", Vox Sang 2000;78 Suppl 2:57-60 (Abstract Only)	
		RESTIFO et al., "The promise of nucleic acid vaccines", Gene Ther 2000 Jan;7(2):89-92 (Abstract Only)	
	-	RYU et al., "Relationships and differentially expressed genes among pancreatic cancers examined by large-scale serial analysis of gene expression", Cancer Res 2002 Feb 1;62(3):819-26 (Abstract Only)	
		SCHIRMBECK et al., "Revealing the potential of DNA-based vaccination: lessons learned from the hepatitis B virus surface antigen", <i>Biol Chem</i> 2001 Apr;382(4):543-52 (Abstract Only)	
		SCHMITTEL et al., "Quantification of tumor-specific T lymphocytes with the ELISPOT assay", <i>J Immunother</i> 2000 May-Jun;23(3):289-95 (Abstract Only)	
		SUAREZ-ALVAREZ et al., "Circulating IgG response to stromelysin-3, collagenase-3, galectin-3 and mesothelin in patients with pharynx/larynx squamous cell carcinoma", <i>Anticancer Res</i> 2001 Sep-Oct;21(5):3677-84 (Abstract Only)	
		SUNDARAM et al., "Synthetic peptides as cancer vaccines", Biopolymers 2002;66(3):200-16 (Abstract Only)	

Date	
	te nsidered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

bstitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known 10/618,088 **Application Number** July 14, 2003 Filing Date Elizabeth Jaffee First Named Inventor **TBD Group Art Unit TBD Examiner Name** 001107.00363 Attorney Docket Number

(use as many sheets as necessary) 8 of Sheet

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of T² the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue Cite Examiner number(s), publisher, city and/or country where published. No. VECINO et al., "Mucosal DNA vaccination with highly attenuated Shigella is superior to attenuated Salmonella and Initials * comparable to intramuscular DNA vaccination for T cells against HIV", Immunol Lett 2002 Jul 3;82(3):197-204 WARD et al., "Immunotherapeutic potential of whole tumour cells", Cancer Immunol Immunother 2002 Sep;51(7):351-7 (Abstract Only) WESTWATER et al., *Development of a P1 phagemid system for the delivery of DNA into Gram-negative bacteria", Microbiology 2002 Apr; 148(Pt 4): 943-50 (Abstract Only) WLAZLO et al., "DNA tumor vaccines", Arch Immunol Ther Exp (Warsz) 2001;49(1):1-11 (Abstract Only) YAMASHITA et al., "Mapping and determination of the cDNA sequence of the Erc gene preferentially expressed in renal cell carcinoma in the Tsc2 gene mutant (Eker) rat model", Biochem Biophys Res Commun 2000 Aug18;275(1):134-40 (Abstract Only) ZOLLER et al., "Active vaccination after allogeneic bone marrow cell transplantation: a new option in the Immunotherapy of cancer?", Arch Immunol Ther Exp (Warsz) 2002;50(3):197-224 (Abstract Only)

Examiner Signature	Date Considered	d
Cignatare		

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any burden nour Statement: This form is estimated to take 2.0 nours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.